IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

DEY, L. P. and DEY, INC.,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	**Civil Action No. 1:09-cv-87**
	)	
TEVA PARENTERAL MEDICINES, INC.,	)	
TEVA PHARMACEUTICALS USA, INC.,	)	**Judge Irene M. Keeley**
and TEVA PHARMACEUTICAL	)	
INDUSTRIES, LTD.,	)	
	)	
Defendants.	)	

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT TEVA'S MOTION *IN LIMINE* TO PRECLUDE ANY EVIDENCE OF OR REFERENCE TO LATE PRODUCED DOCUMENTS

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I. INTRODUCTION

Dey initiated this patent infringement action in 2009 and during the following several years, the parties completed extensive fact discovery, exchanging thousands of documents and conducting numerous depositions. Fact discovery for all purposes closed on January 28, 2011. The parties agreed to a limited extension of fact discovery to December 15, 2011 for the limited purpose of supplementing discovery based on the reexamination of the first family of patents-in-suit in this case. *See* D.I. 104, 106, 109. On the very last day for completion of the reexamination discovery period, Dey unexpectedly produced to Teva additional documents responsive to several of Teva's November 2009 document requests, including laboratory notebooks and other documents related to Dey's Perforomist® NDA. These documents had nothing to do with the reexamination proceedings. Teva objected[1] to Dey's untimely production and the unreasonable delay in producing these documents until after discovery had closed. Dey did nothing, electing not to explain their delay in producing these documents. Since Teva was unable to conduct depositions or otherwise address these late-produced documents during fact discovery, Teva will be unfairly prejudiced if Dey is allowed to introduce or rely on these documents at trial. Teva respectfully requests the Court to preclude Dey from using these untimely produced documents for any reason at trial and to exclude any facts Dey puts forth that finds support in these documents.

II. BACKGROUND FACTS

In November 2009, Teva served its first set of document requests on Dey. Teva requested documents and things relating to, among other topics, Dey's Perforomist® New Drug Application and all laboratory notebooks relating to the subject matter of the patents-in-suit. By early 2011, the parties had exchanged documents and conducted depositions of fact witnesses to

[1] *See* Rivas letter to Giove dated December 23, 2011, attached hereto to the Declaration of Christopher K. Leach in Support of Teva's Motions *In Limine* as Exhibit 1. All exhibits cited herein refer to the corresponding exhibits attached to the Leach declaration.

meet the Court's deadline of January 28, 2011 for the completion of fact discovery. *See* Amended Scheduling Order, (D.I. 86). Following the close of fact discovery, the parties kept to the Court's Amended Scheduling Order, which included completing opening expert reports and the hearing on claim construction. However, in May 2011, before completion of expert discovery, the parties began to discuss how the schedule might be altered to account for the anticipated decision from the pending U.S. Patent Office reexamination of the '344 and '953 patents.[2] The reexamination certificates did not issue until October 2011.[3] As a result, the parties jointly requested a scheduling conference to establish a new discovery and trial schedule. *See* Exh. 5, at pp. 1-2. On November 3, 2011 the parties moved for entry of an amended scheduling order (D.I. 106) requesting a deadline of December 15, 2011 to complete additional fact discovery for the limited purpose of allowing fact discovery relating only to the reexamination of the '344 and '953 patents.[4] The Court approved the joint motion and issued an amended scheduling order setting December 15, 2011 as the deadline for completion of reexamination fact discovery. *See* D.I. 109.

On the deadline for reexamination fact discovery, Dey unexpectedly produced documents responsive to Teva's initial document requests. The documents Dey produced were neither related, nor limited to the reexamination of the '344 and '953 patents. Dey's late production included laboratory notebooks dated from 1999-2001 and correspondence with the FDA relating to Dey's Perforomist® NDA, dated from 2009-2010. These documents were in Dey's possession, custody and control and could have, and should have, been produced in 2009 or 2010, well within the fact discovery period, in ample time for Teva to conduct discovery with this information in hand, and well before the reexamination discovery period was even agreed to

[2] *See* Copeland email to Clark, dated 5-19-2011, (Exh. 3); Haug letter to Judge Keeley, dated 6-1-2011, (Exh. 4).

[3] *See* Haug letter to Judge Kelley, dated 10-11-2011, (Exh. 5); Transcript from status hearing held 10-19-2011, (D.I. 104), at 5:5-8.

[4] Counsel for Dey stated during the hearing: "Your Honor that would include completion—well, completion of fact discovery and I think it's very limited in what needs to be supplemented just based on the re-examination certificates, followed by the expert stage." D.I. 104, at 6:2-5.

by the parties. Teva objected to Dey's unreasonable and unjustified delay in producing these documents and notified Dey that Teva would seek to exclude these documents if Dey intended to rely on them at trial. Dey responded[5], stating only that it reserved the right to rely on the untimely produced documents and that it would oppose any motion to exclude. Dey did not explain why the documents were not produced during discovery.

On May 24, 2013 the parties exchanged proposed trial exhibit lists. Dey's exhibit list includes the laboratory notebook of Dey employee Lisa Voss[6], a laboratory notebook included in Dey's late production of December 15, 2011. Dey's exhibit list is the first time Dey has indicated it will actually rely on the late-produced documents. None of Dey's experts, for example, referred to these laboratory notebooks or FDA correspondence in their expert reports. Due to Dey's unjustified delay in producing these documents until after discovery had closed, Teva was deprived of any opportunity to fully examine and contest Dey's evidence. Teva's litigation strategy and its experts also have been compromised by not having access to this information in a timely manner. Therefore, Teva would be unjustly prejudiced if Dey is allowed to introduce or rely on this evidence at trial.

III. DEY'S LATE PRODUCED DOCUMENTS SHOULD BE EXCLUDED UNDER RULE 37(c)

This Court, under Fed. R. Civ. P. 37(c)(1), has broad discretion to exclude evidence due to Dey's failure to timely provide information as required under Rule 26(e). *See* Fed. R. Civ. P. 37(c)(1). Federal Rules of Civil Procedure 26(b), 33(b), and 34(b) require parties to produce in a timely way relevant documents and other materials in response to the opposing party's discovery requests. Rule 26(e) requires that a party's response to requests for documents "must" be supplemented "in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional information has not otherwise been known to the parties during the discovery process or in writing." Fed. R. Civ. P. 26(e).

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[5] *See* Colletti letter to Rivas, dated December 28, 2011, (Exh. 2).

[6] Dey's proposed PTX 36, Lab Notebook PD-99-22 (Lisa Voss), DEY-TV1653875-912, dated 08/04/1999.

Failure of a party to disclose information as required by Rule 26(e), which the party will seek to support its claims or defenses, will prohibit the party from relying on the untimely produced evidence. "If a party fails to provide information or identify a witness as required by Rule 26(a) or 26(e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at trial, unless the failure was substantially justified or harmless." Fed. R. Civ. P. 37(c)(1); *S. States Rack and Fixture, Inc. v. Sherwin-Williams Co.*, 318 F.3d 592, 595-96 (4th Cir. 2003). The purpose of this exclusionary rule is to prevent surprise and prejudice to the opposing party. *S. States*, 318 F.3d at 596.

Evidentiary rulings under Rule 37(c)(1) are procedural in nature and the law or the regional circuit, in this case, the Fourth Circuit, applies. *See Woods v. DeAngelo Marine Exhaust, Inc.*, 692 F.3d 1272, 1278 (Fed. Cir. 2012); *Wexell v. Komar Indus., Inc.*, 18 F.3d 916, 919 (Fed. Cir. 1994). In the Fourth Circuit, "Rule 37(c)(1) does not require a finding of bad faith or callous disregard of the discovery rules," to preclude evidence from trial. *S. States*, 318 F.3d at 596. The burden is on the nondisclosing party, in this case Dey, to show that its failure to provide information was substantially justified or harmless. *Carr v. Deeds*, 453 F.3d 593, 602 (4th Cir. 2006) (citing *S. States*, 318 F.3d at 596). The five factors that need to be considered to determine whether a nondisclosure of evidence is substantially justified or harmless are: (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the nondisclosing party's explanation for its failure to disclose the evidence. *Blankson-Arkoful v. Sunrise Sr. Living Services, Inc.*, 449 Fed. Appx. 263, 265 (4th Cir. 2011) (quoting *S. States*, 318 F.3d at 597).

IV. DEY'S UNTIMELY PRODUCTION OF DOCUMENTS IS NOT SUBSTANTIALLY JUSTIFIED OR HARMLESS

Dey cannot meet their burden, under the Fourth Circuit's five factor analysis, to establish that their failure to timely produce documents is substantially justified or harmless. First, Dey cannot dispute that their untimely production surprised Teva. The production occurred on the

very last day of the reexamination discovery period despite Teva's November 2009 requests for such documents. When Teva learned of the production, Teva immediately notified Dey that "[w]e were also surprised to see for the first time in Dey's production of December 15, 2011, certain filings and correspondence with the FDA relating to Dey's Perforomist NDA, which date from 2009 and 2010, and laboratory notebooks, which date from 1999-2001." *See* Exh. 1, at p. 2. Second, Dey did nothing to cure the surprise since being notified by Teva in December of 2011. *See* Exh. 2. Further, Dey cannot do anything to cure the surprise for Teva at this late stage of the proceedings. Teva's discovery proceeded as if the information did not exist, Teva's discovery and trial strategy was developed on the basis that this information did not exist, and Teva's experts rendered their opinions under the same premise. Third, allowing Dey to introduce and rely on evidence that Teva has not had a full and fair opportunity to evaluate during fact and expert discovery is not only prejudicial, it would be disruptive and potentially cause delays during the trial. Fourth, Dey has not established the importance of the evidence to its case. Merely listing one of the documents, the Voss laboratory notebook, on their proposed exhibit list is insufficient to show why the information is important. Finally, Dey has offered no explanation why documents responsive to Teva's initial document requests were not produced long before the close of fact discovery in January, 2011, rather than on the very last day of the reexamination discovery period in December 2011, after experts' reports had been exchanged by the parties. Since these are Dey's own documents and bear dates as long ago as 1999, they were well within Dey's possession, custody and control and could, and should, have been produced during fact discovery when Dey, in fact, timely produced a number of other laboratory notebooks. Dey can make no credible argument why laboratory notebooks related to Perforomist® and correspondence with the FDA relating to Dey's Perforomist® NDA were not produced in a timely manner. Indeed, Dey should have been highly sensitive to producing its documents in a timely manner, having repeatedly asked the court to ensure that Teva timely produce Teva's correspondence with the FDA.

Therefore, Dey cannot meet their burden on any of the five factors in the analysis. Dey cannot meet their burden to show that the failure to timely produce documents is substantially justified or harmless. *See Blankson-Arkoful* 449 Fed. Appx. at 265 (granting motion to strike exhibits that were not produced during discovery based on the Fourth Circuit's five factor analysis).

V. TEVA WOULD BE UNFAIRLY PREJUDICED BY DEY'S DELAY IN PRODUCTION OF DOCUMENTS

Teva will be prejudiced if Dey were to be allowed to submit and rely on evidence which Dey had in its possession, custody or control well before the close of discovery, and which Dey had sufficient time and opportunity to timely produce but chose not to. Teva was unable to question any witness regarding the documents, including the Voss notebook, which Dey included on their proposed trial exhibit list. Teva's discovery and litigation strategy has been based on the absence of the information in the late-produced documents and Teva's experts have reached their opinions based on the absence of this information. Due to the unfair prejudice to Teva, Dey should be precluded from introducing or relying on at trial, the late-produced documents, including the Voss laboratory notebook, for any reason.

VI. CONCLUSION

Dey's last minute production of documents is neither substantially justified nor harmless and would prejudice Teva if Dey is allowed to introduce or rely on this evidence at trial. Therefore, Teva respectfully requests that the Court preclude Dey from using Dey's proposed PTX 36, Lab Notebook PD-99-22 (Lisa Voss), DEY-TV1653875-912, for any reason and to exclude any facts Dey attempts to advance based on the late-produced documents.

Dated this 14th day of June 2013.

DEFENDANTS, TEVA PARENTERAL MEDICINES, INC., TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES, LTD., By Counsel:

By: */s/ Bruce M. Gagala*

Bruce M. Gagala (IL State Bar #0901342)
Jeffrey B. Burgan (IL State Bar #6203895)
Leydig, Voit & Mayer, Ltd.
Two Prudential Plaza - Suite 4900
180 North Stetson Avenue
Chicago, IL 60601-6780
Telephone: (312) 616-5600
Facsimile: (312) 616-5700
E-Mail: BGagala@Leydig.com
JBurgan@Leydig.com

/s/ Geraldine S. Roberts

James A. Varner, Sr. (WV State Bar #3853)
Geraldine S. Roberts (WV State Bar #3126)
McNeer, Highland, McMunn and Varner, L.C.
Empire Building - 400 West Main Street
P. O. Drawer 2040
Clarksburg, WV 26302-2040
Telephone: (304) 626-1100
Facsimile: (304) 623-3035
E-Mail: JAVarner@wvlawyers.com
GSRoberts@wvlawyers.com

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CERTIFICATE OF SERVICE

This certifies that on this 14th day of June 2013, counsel for the defendants served the following document: "**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT TEVA'S MOTION *IN LIMINE* TO PRECLUDE ANY EVIDENCE OF OR REFERENCE TO LATE PRODUCED DOCUMENTS**" upon counsel of record via: (1) electronic notification through the Court's CM/ECF system; and/or (2) via facsimile, and/or (3) via hand delivery, and/or (4) via electronic mail transmission as previously agreed upon by the parties:

Gordon H. Copland, Esquire
William J. O'Brien, Esquire
Steptoe & Johnson PLLC
400 White Oaks Blvd.
Bridgeport, WV 26330
Fax (304) 933-8183

David R. Marriott, Esquire
David N. Greenwald, Esquire
Evan R. Chesler, Esquire
Roger G. Brooks, Esquire
Cravath, Swaine & Moore LLP
825 Eighth Avenue
New York, NY 10019
Fax (212) 474-3700

Co-Counsel for Plaintiffs

/s/ Geraldine S. Roberts
Geraldine S. Roberts (WV State Bar #3126)